SIEMENS

JUN 2 4 2014

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K133816

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Ernest Joseph Senior Manager, Regulatory Affairs
Phone Number:	(914)-524-2431
Fax Number:	(914)-524-2101
E-mail Address:	Ernest.joseph@siemens.com
Date Prepared:	May 21, 2014

2. **Device Name**

Proprietary Name:	IMMULITE® 2000 Free PSA Calibration Verification Material (CVM)
Measurand:	
Type of Test:	21 CFR 862.1660, Quality Control Material Class I Reserved
Regulation Section:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Classification:	
Products Code:	Clinical Chemistry (75)
Panel:	IMMULITE® 2000 PSA Calibration Verification Material

3. **Predicate Device Name**

Predicate 510(k) No:	K131536

4. **Device Description:** IMMULITE® 2000 Free PSA Calibration Verification Material (CVM) contains one set of four vials (LPFCVM1-4), 2 mL each. LPFCVM1 contains bovine protein/buffer matrix with preservatives. LPFCVM2, LPFCVM3 and LPFCVM4 contain low, intermediate and high levels of Free PSA respectively, in human-source matrix with preservatives. The CVMs are supplied lyophilized form.

5. **Intended Use:**

Indication for Use:	See Indications for Use Statement below The IMMULITE® Free PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of Free PSA antigen.
Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Free PSA CVM is substantially equivalent to the predicate device, IMMULITE® 2000 PSA CVM, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device **IMMULITE 2000 Free PSA CVM**	**Predicate Device** **IMMULITE 2000 PSA CVM**
Intended Use	The IMMULITE® Free PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of Free PSA antigen	The IMMULITE® 2000 PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of PSA antigen
Levels	4	4
Stability	Stable unopened until the expiration date	Stable unopened until the expiration date
Storage	≤-20°C	≤-20°C
Use	Single Use Only	Single Use Only

DIFFERENCES		
	Candidate Device **IMMULITE 2000 Free PSA CVM**	**Predicate Device** **IMMULITE 2000 PSA CVM**
Analyte	Free PSA	PSA
Form	Lyophilized	Liquid
Matrix	Bovine Serum Albumin	Processed (pH-treated) Chicken Serum

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate the shelf life claim for the IMMULITE® 2000 Free PSA Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platform throughout the established shelf life of the CVM. The IMMULITE® 2000 Free PSA Calibration Verification Material (CVM) stability study performed with CVM lot 15 shows acceptable results up to 3.5 years when stored at -20°C, and

for on-going stability for lots 90 and 91 shows acceptable results up to 6 months at this time when stored at -20°C. Therefore the current shelf life stability claim is 6 months.

7.1.1 Stability Protocol Summary:
The CVMs are run as part of the calibrator stability testing. The stability calibrators/CVMs are run in duplicate (as a minimum) and the concentration value is determined from the reference internal calibration curve. Stability calibrators/CVMs are run at 6 months then annually up to the month after expiry. The stability will be tested at 24, 36 and 42 months.

7.1.2 Stability Acceptance Criteria Summary:
The Acceptance Criteria for the IMMULITE Free PSA Calibration Verification Material (CVM) requires that the dose concentration for the stability CVM is within 10% of assigned dose concentration.

Table 2: Stability Acceptance Criteria for IMMULITE 2000 Free PSA CVM

CVM Level	Assigned Dose (ng free PSA/mL)	Acceptance Criteria (% difference to assigned dose)	Acceptable Range (ng free PSA/mL)
LPFCVM1	**0.00**	**N/A**	**N/A**
LPFCVM2	**0.20**	**±10**	**0.18 – 0.22**
LPFCVM3	**1.45**	**±10**	**1.31 – 1.60**
LPFCVM4	**24.40**	**±10**	**21.96 – 26.84**

7.2 Traceability:
The IMMULITE Free PSA CVMs are traceable to WHO 1st NIBSC IS (96/668). The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment, Expected Values and Reference Range:
Free PSA CVMs are 4 level materials which are subset of 11 level Free PSA calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Free PSA reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using Free PSA antigen stock and are traceable to internal material which has been gravimetrically prepared. Three levels of commercially available controls and 20 normal male patient samples, 10 spiked samples and 10 PSA patient samples were used to validate CVM value assignments.

The Free PSA CVM level were tested on 18 replicates in total comprised of 6 runs and 3 replicates per run on 4 IMMULITE 2000 system analyzers and 2 different reagent kit lots. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averages across all systems. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected assay range is 0.07 - 25.0 ng/mL. The controls must fall within their target ranges and the target specifications are shown in **Table 4**.

Table 4: Analyte Target Range Levels

Analyte Target Levels	Level	REF and Lot number	Target Mean (ng/mL)	SD	Guideline ± 2SD Range (ng/mL)	
	CVM1	LPFCVM1 015	0.00		0.00	0.07
	CVM2	LPFCVM2 015	0.20	0.0125	0.17	0.22
	CVM3	LPFCVM3 015	1.45	0.08	1.29	1.61
	CVM4	LPFCVM4 015	24.40	1.2	22.0	26.8*
Assay Range		0.07 – 25.0 ng/mL				

* The upper limit for this CVM exceeds the assay range of 25.0 ng/mL. The range of the CVM is determined from the precision %CV around the target. The upper limit of this CVM is within +10% of the assay range which ensures the whole of the assay range is covered.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Free PSA Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed, IMMULITE® 2000 PSA Calibration Verification Material. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, The IMMULITE® 2000 Free PSA Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SIEMENS HEALTHCARE DIAGNOSTICS INC.
MR. ERNEST JOSEPH
SENIOR MANAGER, REGULATORY AFFAIRS
511 BENEDICT AVENUE
TARRYTOWN, NY 10591

June 24, 2014

Re: K133816
Trade/Device Name: IMMULITE 2000 Free PSA Calibration Verification Material (CVM)
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I
Product Code: JJX
Dated: June 16, 2016
Received: June 17, 2014

Dear Mr. Joseph:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth A. Stafford -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k133816

Device Name
IMMULITE® 2000 Free PSA Calibration Verification Material

Indications for Use *(Describe)*
The IMMULITE® Free PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of Free PSA antigen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Stafford -S